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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,458	08/01/2003	Sophie Chen	CSO-0001-P	2036
23413 7590 11/16/2007 CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002				
			EXAMINER KRASS, FREDERICK F	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 11/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/647,458

Applicant(s)

CHEN, SOPHIE

Examiner

Frederick Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 4,7-17,25,31 and 37-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,18-24,26-30,32-36,44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Previous Rejections

Unless specifically repeated/maintained infra, all previous rejections are withdrawn.

Since the new grounds of rejection which follow were not necessitated by applicant's amendment, this action is NON-FINAL.

Claim Informalities

The following informalities are noted and should be corrected in responding to this Office action:

- 1) Claim 3 ends in two periods; one should be deleted.
- 2) Claim 18, first line, a capital "T" should be inserted to begin the claim.
- 3) The status identifiers of claim 7, 38 and 39 would appear to be incorrect, insofar as those claims are drawn to non-elected species and thus the claims should be identified as being withdrawn.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The construction of claim 35 is non-sequitur insofar as it depends from itself. Correction is required.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5, 6, 18-24, 26-30, 32-36, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 09-176011 (machine translation) in view of Camden (USP 6,498,188).

The primary reference discloses the use of various flavonoids as chemotherapeutic agents. Since the flavonoid is used to improve the effectiveness of chemotherapy via the mechanistic commonality of heat shock protein stabilization (see paragraph 0003 of the machine translation text), it would be expected to be effective against a wide array of cancers of varying etiology, including drug-resistant variants. Wogonin is specifically tested in the working examples (see especially the last three lines of paragraph 0039).¹ Since that testing is done in cell lines, the prior art differs from the instant claims insofar as it fails to set forth specific dosages for that particular flavonoid, although it does more generally suggest the use of up to 99 percent by weight flavonoid at paragraph 0030. (Similarly, the reference does not provide specific direction concerning the use of wogonin in combination therapy with other chemotherapeutic agents, including immunomodulators).

The secondary reference illustrates the state of the art of cancer chemotherapy. As disclosed therein, combination chemotherapies are well known, with the particular members of the combination being tailored to the particular cancer being treated. Members of the combinations include any of a number of well known chemotherapeutic agents for use against a

¹ The prior art clearly suggests the flavonoid can be provided in the form of its extract. See paragraph 0023. That, coupled with the suggested use of *Scutallaria* derived flavonoids in paragraph 0016, is viewed as fairly suggesting the use of the extracts of instant claim 5 (the well-known commercial source of wogonin and other related compounds).

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wide variety of cancers (see the passage bridging column 5, line 3 to column 11, line 20) as well as any of a number of well known immunomodulators such as interferons (see the passage bridging column 11, line 32 to column 12, line 51); selection of appropriate dosages and administrative routes is a matter of routine experimentation (see the passage bridging column 12, line 55 to column 18, line 4). The secondary reference differs from the instant claims insofar as phytoestrogens such as wogonin are not specifically disclosed.

It would have been obvious to have administered wogonin to patients to provide chemotherapy having improved effectiveness as disclosed by the primary reference, tailoring treatment as required to optimize performance by including additional known chemotherapeutic agents and/or immunomodulators as taught by the secondary reference.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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